REMARKS

The following remarks are submitted to be fully responsive to the final Official Action dated March 28, 2008. This response is thus timely submitted within the three-month shortened statutory period for response. Should any fees be required, the Commissioner is authorized to charge Kagan Binder Deposit Account No. 50-1775 and thereafter notify us of the same. Reconsideration of all outstanding grounds of the rejection and allowance of the subject application are believed in order and respectfully requested.

Claims 1-4, 8, 9 and 11-13 are pending in the above-identified patent application. Claims 1-4 were previously withdrawn. Claims 8, 9 and 11-13 have been rejected.

In the Official Action, claims 8, 9 and 11-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,395,014 to Macoviak et al. (hereinafter "Macoviak '014") and in view of U.S. 6,059,757 to Macoviak et al. (hereinafter "Macoviak '757").

In the 103(a) rejection, the Official Action provides that Macoviak '014 discloses all of the features of independent claim 8 except "is silent" with regard to the feature of "valve seating retaining ring fixed on the proximal end of the tube; wherein the membrane is tethered to the valve seating retaining ring at multiple spaced apart fixation points around the circumference of the ring." The Official Action goes on to provide that Macoviak '757 "discloses a valve membrane assembly comprising a valve seating retaining ring (element 20 in Fig. 1, 1(a)-1(b)); a membrane 22 attached to the retaining ring at multiple spaced fixation points around the circumference of the ring; wherein the retaining ring is attached to a catheter via element 18," and that it would have been obvious to use such a valve membrane assembly of Macoviak '757 in Macoviak '014 since Macoviak '014 discloses that the reference is capable of using the valve membrane assembly of Macoviak '757. Further, the Official Action provides that the combination of Macoviak '014 and Macoviak '757 is "still silent with regards to the retainer ring being fixed on the proximal end of the elongated tube," but that the device in Fig. 16 of Macoviak '014 includes a valve assembly adjacent the open proximal end of the elongated tube, and that it would have been obvious to integrate the valve assembly with the elongated tube.

Macoviak '014 discloses a device used during cardiopulmonary bypass surgery that is an arterial perfusion catheter with a deployable cerebral embolic protection assembly (CEPA) for protecting a patient from adverse effects due to emboli that may be dislodged during surgery (Macoviak '014: col. 1, lines 22-26). Various embodiments of the device are disclosed, with the embodiment discussed in the Official Action being the one illustrated in Figure 16. The device in Figure 16 is described as having a CEPA in the form of an embolic filter assembly 642

combined with a selectively deployable external flow control valve 644 (Macoviak '014: col. 10, lines 43-46). The selectively deployable external catheter flow control valve 644 is not described in the specification, but rather three U.S. patent applications (now U.S. Pat. Nos. 5,827,237 ("'237 patent"), 6,896,690 ("'690 patent") and Macoviak '757) were incorporated by reference for their descriptions of such valves (Macoviak '014: col. 10, lines 55-60).

Macoviak '757 describes a valve 10 (e.g., see Figs. 1 and 2 of Macoviak '757) coupled to a catheter 14 at an exterior 16 of the catheter 14. The valve 10 is comprised of leaflets 22 (Macoviak '757: col. 7, lines 32; col. 8, lines 13-14). Advancement and retraction members 18 are shown in both Figs. 1 and 2 as being coupled to a portion of the catheter 14 and to leaflets 22. The advancement and retraction members 18 are described as being made of material such as "shaped memory metal, stainless steel and the like" (Macoviak '757: col. 7, lines 27-30). The members 18 thereby function as leaf springs that bias the leaflets 22 either toward or away from the catheter 14 depending upon the embodiment. The members 18 put the edge of leaflets 22 into a default operable position.

With regard to the embodiment shown in Fig. 1, the specification erroneously describes the figure as showing the advancement and retraction members 18 coupled to the distal portion of the catheter at attachment point 20 (col. 7, lines 25-27). In fact, attachment point 20 in Fig. 1 is located where advancement and retraction members 18 and the proximal ends of the leaflets 22 are attached. Figs. 1(a) and 1(b) also show the attachment point 20 located on or near an outer surface of each leaflet 22. In the description and shown in Fig. 2, the advancement and retraction members 18 are correctly described as being attached to the leaflets 22 (Macoviak '757: col. 8, lines 14-15). In both cases, whether described correctly or not in the specification, an attachment member 20 is located where an advancement and retraction member 18 and a leaflet 22 are joined together.

Figure 1 of Macoviak '757 shows that antegrade flow of blood through the circulatory vessel causes the leaflets 22 to be displaced from catheter 14 and pushed against the wall of the circulatory vessel (leaflets 22 shown in dashed lines) (Macoviak '757: col. 7, lines 64-66). Retrograde blood flow then causes the distal ends of leaflets 22 to move back towards the catheter 14 under the influence of members 18, thereby preventing blood from flowing backwards (Macoviak '757: col. 7, line 67 – col. 8, line 2). In the embodiment in Fig. 2, on the other hand, antegrade blood flow causes the leaflets 22 to be displaced toward the catheter 14 (Macoviak '757: col. 7, lines 64-66; col. 8, lines 18-20), and retrograde blood flow causes the leaflets 22 to be pushed against the wall of the circulatory vessel 12 under the influence of

members 18, thereby preventing blood from flowing backwards (Macoviak '757: col. 8, lines 21-25, 28-31).

In response to the rejection, first, Applicants assert that the Official Action mischaracterizes the disclosure of Macoviak '757. Specifically, the feature indicated by 20 in Figs. 1, 1(a), 1(b) and 2 is not a valve seating retaining ring, as indicated in the Official Action. Attachment point 20 is just that: a point where an advancement and retraction member 18 is attached to a leaflet 22. There is no description in the specification of attachment member 20 being a ring of any kind, and specifically not a ring that is both attached to an end of a filter tube and has a membrane connected to its inner surface such that expansion and compression of the membrane expands and compresses the ring and the end of the filter tube, as in the present application. The valve seating retaining ring of the present application functions completely differently from the attachment member 20 of Macoviak '757. In the present application, expansion of the membrane causes the valve retaining ring to be pushed up against the inner circumference of a vessel wall. The attachment point 20 in Macoviak '757 does not do the same thing. In fact, the specification and figures of Macoviak '014 teach and illustrate that it is the leaflets 22 that are pushed up against the vessel wall during antegrade flow in Fig 1 and during retrograde flow in Fig. 2.

Thus, there is no valve seating retaining ring taught in Macoviak '757. Therefore, together Macoviak '014 and Macoviak '757 do not present all elements of independent claim 8 and do not render claim 8, nor dependent claims 9, 11-13, unpatentable.

Second, if the valve 644 of Macoviak '014 was modified to be like that of valve 10 in Macoviak '757, the combination would not result in a valve like that in the present application. If the Macoviak '757 valve 10 was placed in the CEPA assembly of Macoviak '014, the valve would be connected to the catheter 646 using advancement and retraction members or such equivalents. Such a modification would still not result in a valved filter device like that in the present application. The valve portion would not be connected to the filter portion. The valve leaflets would not be tethered to the inner surface of a valve seating retaining ring at discrete points, but would instead be connected to the catheter 646 using advancement and retraction members or equivalents thereof. Thus, expansion of the leaflets would not push against a proximal end of an elongated tube of filter material.

Third, as noted by the Official Action, neither reference teaches a retainer ring being fixed on the proximal end of an elongated tube of filter material, as in claim 8. The Official Action provides, however, that it would have been obvious to integrate a retainer ring with the

elongated tube to form one piece, because "an article which has formerly been formed in two pieces and put together involves only routine skill in the art." Again, as discussed above, the two references do not disclose, teach or suggest a valve seating retaining ring, so such a ring can not possibly be fixed to the proximal end of the filter tube, as in claim 8. Furthermore, Macoviak '014 provides with regard to the embodiment shown in Fig. 16 that the valve and filter are separate and specifically that the valve 644 is mounted on the catheter shaft 646 upstream of the filter 642 (Macoviak '014: col. 10, lines 48-51). Therefore, the combination of references do not teach or suggest a way to connect the valve to the filter portion, such as by using a valve seating retaining ring. Furthermore, the two pieces (valve and filter) that are taught by the combination of Macoviak '014 and Macoviak '757 are not the same as the valve and filter portions of the present application. Thus, the valved filter device of the present application is not "an article which has formerly been formed in two pieces and put together," as indicated by the Examiner.

In sum, Macoviak '014 and Macoviak '757 do not teach all of the elements of claim 8 of the present application. Even if the references are combined, they do not teach or suggest connection of a valve portion to a filter portion. In particular, the references do not disclose use of a valve seating ring or equivalent to join the valve and filter portions. Even if the references were combined and found to disclose a ring, the leaflets would not be attached to such a ring, but instead would be attached to the catheter. Macoviak '014 and Macoviak '757 thereby do not render claim 8, nor its dependent claims 9 and 11-13, unpatentable. Withdrawal of the 103 rejection is therefore respectfully requested.

Additionally, with regard to the dependent claims, the claims add further distinguishing features from the combination of Macoviak '014 and Macoviak '757. For example, dependent claim 13 adds the feature that expansion and compression of the membrane expands and compresses the valve seating retaining ring and the proximal end of the filter tube. There is no retaining ring disclosed in the two references, nor is there a teaching that the valve and filter portions be attached. Therefore, even if a retaining ring is construed as being disclosed by Macoviak '757, it is not possible for expansion or compression of the ring to expand and compress the filter tube, since the valve and filter are not attached.

Conclusion

It is submitted that claims 8, 9 and 11-13 are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

By: _____

Kimberly S. Zillig, Reg. No. 46,346
Customer Number 33072
Phone: 651-275-9846
Facsimile: 651-351-2954

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